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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,749	01/12/2001	Vladimir Puskaric	1326	4891

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/759,749	<b>Applicant(s)</b> PUSKARIC, VLADIMIR	
	<b>Examiner</b> Ashwin Mehta	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1,2,4-10,15,16,21,23-27,37-43 and 50-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4,5,7,8,21,23,24,26,27 and 40 is/are allowed.
- 6) ☒ Claim(s) 6,9,10,15,16,25,37-39,41-43 and 50-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

a) ☐ All   b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The rejections of claims 3, 5, 12, 13, 22, 24, 30-33, 40-44, and 47-49 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, are withdrawn, in light of the claim amendments or cancellations.

3. The rejection of claims 13, 17, 32, 33, 36, 41, and 43 under 35 U.S.C. 102/103 is withdrawn, in light of the claim cancellations or amendments.

### *Specification*

¶ 6. The amendment filed 11 April 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: Table A inserted on page 16 after line 23.

Applicant is required to cancel the new matter in the reply to this Office Action.

### *Claim Rejections - 35 USC § 112*

¶ 7. Claims 6, 25, 50-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claims 6 and 25: the recitation "capable of expressing" in line 2 renders the claim indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation be replaced with --and having--.

In claims 50-57: the recitation "PH5TG" in claims 50-52, and 54-56 render the claims and those dependent thereon indefinite. Since the name "PH5TG" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "PH5TG" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and the specific characteristics associated therewith could be modified. Amending claims 50 and 54 to recite the ATCC deposit number in which seed of corn inbred line PH5TG has been deposited would overcome the rejection.

In claim 51: the claim recites "The backcross conversion PH5TG maize plant of claim 50" in line 1. However, claim 50 is directed to a method, not a plant.

In claim 55: the claim recites "The transgenic PH5TG maize plant of claim 54" in line 1. However, claim 54 is directed to a method.

6 -8. Claims 9, 10, 15, 16, 37-39, and 41-43 remain and claims 50-54 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 13 January 2003 under item 7. Applicant traverses the rejection in the paper filed 11 April 2003. Applicant's arguments were fully considered but were not found persuasive.

Regarding claims 9 and 10, Applicants argue that one of ordinary skill in the art would be able to run a molecular profile on PH5TG and the F1 hybrid and be able to identify the F1 hybrid as being produced from PH5TG, and that seed pericarp tissue can be used to discern the maternal or paternal origin of the allele sets if necessary. Applicant argues that SSR and RFLP techniques can be used to analyze F1 hybrids and determine if one of its parents is PH5TG (response, page 12, 1<sup>st</sup> and 2<sup>nd</sup> full paragraphs). However, SSR and RFLP data were not described in the specification as originally filed. Further, Applicants do not correlate any functions with any SSR or RFLP markers. One skilled in the art cannot correlate any traits expressed by the claimed plants with any molecular markers. Moreover, Applicant does not describe the genotypic or phenotypic contribution from the other parent, and hence the broad claim to all F1 hybrid plants produced from the disclosed inbred plant lack adequate written description.

Regarding claims 15 and 16, Applicant argues that anyone of skill in the art would know how to utilize the well-established breeding methods with PH5TG (response, page 12, 3<sup>rd</sup> full paragraph). However, the claimed method requires the use of descendants of PH5TG, which are not described. A method is not fully described if components required for the method are not described. Applicant argues that claim 41 is drawn to the F1 plant produced by the method of claim 40, and is identifiable through both breeding records and molecular marker techniques, as discussed (response, page 13, 1<sup>st</sup> paragraph). However, breeding records and markers do not

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describe the morphological and physiological traits expressed by the F1 plants. Applicant argues that claim 42 is drawn to the method of selfing the F1 for successive filial generations, and claim 43 is drawn to plants derived from that method that have at least 50% of their genetics derived from PH5TG (response, page 13, 1<sup>st</sup> paragraph). As discussed, if all of the components needed for claimed methods are not described, the method is not described. The F1 plants need for the method of claim 42 is not described. The traits expressed by the plants of claim 43 are not described, and are not correlated with any markers from PH5TG.

Applicant further argues that a molecular profile of line PH5TG is supplied in a declaration signed by Dr. Dinakar Bhatramakki (an employee of the assignee of the instant application). Applicants argue that the specification has also been amended to include the SSR profile of PH5TG that is supplied in the declaration. Applicants argue that this is not new matter, as it is an inherent feature of PH5TG, which has been deposited with the ATCC.

Applicant cites *Ex parte Marsili, Rosetti, and Pasqualucci* in support, stating that in *Marsili*, the Patent and Trademark Office Board of Appeals concluded that the products described had and have now the structure given in the amendment in question, and the changes made in the amendment do not constitute new matter (response, paragraph bridging pages 13-14). However, the issue in *Marsili* is not analogous. On page 905 of *Marsili*, the Court states that the amendment in *Marsili* was not new matter because it merely constituted a correction of a previously submitted description of a compound, which is permissible. In the instant amendment, however, the newly introduced SSR data represents newly added data, and is not merely a correction of existing data. The addition of new characteristics remains impermissible. In *Marsili*, the specification disclosed a chemical structure for a compound, and the amendment

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merely corrected an error in the structure. In the instant case, no SSR data was present in the original specification, and the newly presented SSR data represents new matter.

Applicants also argue that the test of written description is not whether the morphological and physiological traits of the PH5TG progeny are described, but whether subject matter was described in such a way to convey to one of ordinary skill in the art that the inventor had possession of the claimed invention. Applicants continue, arguing that while PVP is distinct from patents, the scope of protection conferred by PVP provides a clear indication that breeders of ordinary skill in the art consider mutations, F1 hybrids, backcross conversions, and transgenic conversions to be within the scope of the invention of the variety itself. The fact that the progeny have not been created does not prevent them from being protected in this manner (response, paragraph bridging pages 14-15). However, the originally filed specification only describes the deposited inbred line in terms of its morphological and physiological traits, not its genotype. As information concerning the genome of PH5TG was not known at the time of filing, molecular information cannot be used to describe progeny of PH5TG. Further, as Applicant admits, the requirements for PVP and patentability are distinct.

Regarding claims 37-39, Applicant argues that the claims are directed to growing out F1 hybrid in which PH5TG is a parent and searching for PH5TG inbred seed, and that the claim is described in the specification on pages 5-6 (response, page 15, 2<sup>nd</sup> full paragraph). However, as discussed above, the claims are included in the rejection because the method encompasses the use of products that are not described.

Regarding claims to transgenic PH5TG, PH5TG comprising backcross conversions, and new claims 50-57, Applicants argue that examples of transgenes, genes and traits that can be

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backcrossed into the PH5TG are given in the specification, and that in order to expedite prosecution, new claims 51 and 55 list the type of traits that may be conferred by backcross conversions and transgenes (response, paragraph bridging pages 15-16 and page 16, 1<sup>st</sup> full paragraph). However, claims 50 and 54 do not list the types of genes contemplated, and the effect on the description of the plant produced is unknown. Further, the specification does not describe any plants that were produced by backcrosses that are exactly the same as PH5TG except for the introduced gene. Applicants argue that breeders, by using molecular markers, may obtain up to 98% genome identity between the backcross conversion and the recurrent parent after two backcrosses, and cite Openshaw et al. for support (response, page 116, 1<sup>st</sup> paragraph). However, Table 1 in the reference appears to indicate that only 87.5% of the recurrent parent genome is recovered after two backcrosses, and only assuming that there is no linkage to the gene being transferred. Further, the results referred to by Applicant were of computer simulations. Real field data showed that the recovery of the recurrent parent was lower after two backcross generations (page 42). Furthermore, the computer simulations of Openshaw et al. assume the absence of linkage of the allele being transferred from the donor parent. Moreover, even if 98% genome identity is obtained between the backcross conversion and recurrent parent, the remaining 2%, given the size of the maize genome, would encode for traits not described by Applicant. The specification also does not describe other nonselected traits and genes transferred during the first cross, and which not selected out. Furtherstill, the instant disclosure did not describe any molecular marker data for PH5TG at the time of filing. Applicant cites Wych for teaching that the backcrossing has been used since the 1950s, Poehman et al. for teaching that a backcross-derived inbred line fits into the same hybrid combination as the recurrent parent



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inbred line and contributes the effect of the additional gene (response, paragraph bridging pages 16-17). However, neither reference indicates that the plant comprising the single gene conversion is exactly the same except for the added gene. Applicants also provide a declaration signed by Dr. Stephen Smith (an employee of the assignee of the instant application) which, Applicants argue, explains how genetic analysis was used to identify backcross conversion inbreds of PH5TG (response, page 17, last paragraph). However, it is noted that the analysis was conducted according to the teachings of articles that were published after the filing of the instant application, and cannot be relied upon by Applicants.

7.9. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection.

There is no descriptive support in the specification for the recitation "at least 50% genetic contribution from".

8.10. Claims 37-39 and 50-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 13 January 2003 for claims 18-20 and 47-49 under item

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¶ 8. Applicant traverses the rejection in the paper submitted 11 April 2003. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that Hunsberger et al. succeeded in incorporating a gene into petunia plants of different genetic backgrounds, and cites Hallauer et al. for teaching that for single gene traits, the backcross method is relatively easy to manage (response, paragraph bridging pages 18-19). However, Hunsberger et al. teach failures as well. Hallauer et al. do not teach that the genome of the recurrent parent can be completely recovered in only two crosses. Further, the claims do not indicate that single genes are backcrossed, but rather a trait is backcrossed, which encompasses all traits, regardless of complexity. Applicant argues that Kraft et al. do not teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising single gene conversions, and that the teachings of the reference are in relation to sugar beet, not maize (response, page 19, 1<sup>st</sup> full paragraph). However, Kraft et al. do teach the unpredictability inherent in the construction of genetic maps based upon molecular marker data, which counters Applicant's assertions that such maps may be constructed here.

Applicant also argues that the concept of an essentially derived variety was introduced into the 1991 Act of the UPOV convention, and that such varieties may be obtained by backcrossing (response, page 19, 2<sup>nd</sup> full paragraph). However, the USPTO is not subject to UPOV Convention rules, as Article 35(2) of the 1991 UPOV Convention Act ensures that the United States adheres to its patent system.

Applicant argues that Eshed et al. teach that selected QTL in maize did not show a less than additive trend (response, page 20, 2<sup>nd</sup> full paragraph). However, it is not clear that this is

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true for all loci. Further, as discussed above, Openshaw et al. teach that two backcross generations recover only 87.5% of the recurrent parent genome.

Further, the issue concerns whether a single gene or single trait alone can be brought into the inbred by backcross conversion. In the outcross, different alleles at all loci are introduced. During the backcross, particular traits are selected for. The specification only teaches a small number of the myriad traits of the deposited line. The other traits at the multitude of other alleles are not taught. Applicants then fail to provide guidance from plants derived from the deposited inbred line by backcross conversion, that have only a single gene or single trait difference.

Claims 37-39 have been included in this rejection, as the specification does not teach how one would distinguish the inbred plants from all of the other types of hybrid plants in the collection. The specification does not teach any phenotypic or genotypic information for any of the hybrids, nor does the specification as originally filed teach any genotypic information for PH5TG. In the absence of further guidance, undue experimentation would be required by one skilled in the art to distinguish PH5TG plants from all of the different hybrids plants grown from the collection of seed.

Claim 37 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of transforming PH5TG when the transgene is known in the art and whose effect when expressed in transformed plants is known, does not reasonably provide enablement for the claimed method with all transgenes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The claim is broadly drawn towards a method of developing a transgenic PH5TG maize plant wherein inbred maize plant PH5TG is transformed with any transgene.

The specification teaches morphological and physiological traits expressed by inbred maize plant PH5TG, and that PH5TG seed has been deposited with the ATCC under Accession No. PTA-4526 (Table 1; page 52). The specification indicates that PH5TG may be transformed with transgene(s), and provides examples of some particular transgenes known in the art (page 22, line 34 to page 34, line 24).

However, the specification does not enable transforming maize plant PH5TG with all transgenes. As broadly interpreted, the method encompasses introducing any type of transgene into PH5TG, including those that have not been isolated at the time the application was filed. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Further, if the effect of transgene expression in PH5TG is unknown, one skilled in the art would not know how to use the transformed plant. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art, must supply the enabling aspects of the invention. Furthermore, the effects of transgene expression on the traits expressed by untransformed PH5TG are unknown. The specification does not teach one how to use a transformed PH5TG plant if all of the morphological and physiological traits of PH5TG are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue

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experimentation would be required by one skilled in the art to make and use the claimed invention.

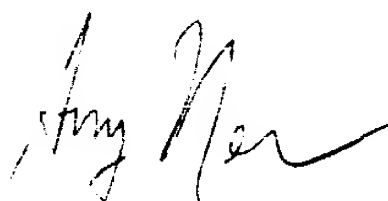
***Summary***

~~1012.~~ Claims 1, 2, 4, 5, 7, 8, 21, 23, 24, 26, 27, and 40 are allowed. Claims 9, 10, 15, 16, 37-39, and 41-43 remain and claims 6, 25, and 50-57 are rejected.


***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0190.

June 20, 2003



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